Strengthening and Upgradation of existing healthcare institutions under Central Government are undertaken as per the need and available resources.

The National Rural Health Mission envisages strengthening of public health facilities by Upgradation of Sub-centres, PHCs, CHCs and district hospitals to Indian Public Health Standards, providing for essential equipments, drugs and manpower as per the District Programme Implementation Plans (PIPs) of the States.

Further, under the Pradhan Mantri Swasthya Suraksha Yojana (PMSSY), it has been decided to set up one AIIMS-like institution each in the State of Bihar, Chhattisgarh, Madhya Pradesh, Orissa, Rajasthan and Uttaranchal and also to upgrade to AIIMS level 13 existing State Government Medical Institutions.

Guidelines for human clinical trials

3108. SHRI P.R. RAJAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Indian Council of Medical Research (ICMR) have conducted any survey regarding the guidelines followed by the Indian Institutional Committees during human clinical trials;

(b) if so, the details including number and the details of the Institutional Committees which are not following the guidelines;

(c) if so, the action taken, if any, against the Institutional Committees for violation of the guidelines; and

(d) the details of number of clinical trials convened in the country for last three years, year-wise, category-wise and State-wise?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (c) Indian Council of Medical Research (ICMR) has issued Ethical Guidelines for clinical research on human subjects including clinical trials of drugs, diagnostics and vaccines in 1980 which was revised in 2000. According to these guidelines all institutions doing clinical research should have an Institutional Ethics Committee (IEC) for giving approval for these studies. Under the Drug and Cosmetic Act also all institutions should have Ethics Committee approval before initiating the trial in addition to other provisions for clinical trials. The Indian Good Clinical Practice (GCP) guidelines 2002

and the Schedule Y for clinical trials also give detailed requirements. ICMR conducted a survey of Institutional Ethics Committee during 2003-04. Out of the 233 institutions who responded, 178 had IECs. ICMR and GCP guidelines prescribed the structure and procedures to be followed by the IECs. The survey indicated that by and large the existing Committees are constituted as per the guidelines. Steps have already been initiated to legislate the ICMR Ethical Guidelines into an Act so that it becomes mandatory that all institutions doing clinical research should have IEC as per proposed norms.

(d) There are 200 clinical trials approved by regulatory authority received in the last three years. Category-wise and State-wise information about these clinical trials is not maintained.

Hepatitis Vaccine

†3109. SHRI KRISHAN LAL BALMIKI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of the fact that the Hepatitis disease is taking a serious turn by taking more and more people in its grip.

(b) whether Government hospitals are well equipped with the Hepatitis vaccine; and

(c) if so, the details in this regard?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (c) There are five common types of Hepatitis, viz., A, B, C, D and E. Hepatitis—A is benign as compared to others. Out of the remaining four, there is vaccine only for prevention of Hepatitis B. India has the second largest pool of Hepatitis B virus (HBV) carriers in the world and contributes to nearly 15% of the entire pool of HBV carriers in the world.

Hepatitis B is preventable by ensuring precautionary measures, including vaccination. The Government has launched a pilot project for immunization against Hepatitis B free of cost for children below one year only. Hepatitis B vaccination has commenced and is continuing in 15 cities since 2002-03 and in 32 districts and in Andaman & Nicobar islands since 2003-04. Besides, vaccine for Hepatitis B is available in the country at affordable prices.

†Original notice of the question was received in Hindi